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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/19/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|------------------------|--|
| Offic Action Summary | Application No. | Applicant(s) |
| | 09/519,295 | MATHEWS, HALLETT H. <i>[Signature]</i> |
| | Examiner | Art Unit |
| | Julian W. Woo | 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 30-33 is/are allowed.
- 6) Claim(s) 18,19,22-24 and 26-28 is/are rejected.
- 7) Claim(s) 20,21,25,29 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,11,12</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Objections***

1. Claim 23 is objected to because of an informality, which can be corrected as follows: In line 1, "23" should be replaced by --22--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Smith (4,862,891). Smith discloses, in figure 1 and in col. 6, lines 4-10, a three dilator system with a first tubular dilator (22), a second tubular dilator (21), and a third tubular dilator (20) configured as claimed.
4. Claims 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison (3,486,505). Morrison discloses, in figures 1 and 2 and in col. 2, lines 10-69, a method for fixing adjacent vertebrae, where skin and tissue ("soft tissues") are sequentially dilated with an incision and movement of the lateral guides (16) and arms (11), fusing the adjacent vertebrae is performed with a material (bone graft, C), and fixation instrumentation (11, 14) is secured to the adjacent vertebrae.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Kambin (4,573,448). Smith discloses the invention substantially as claimed, but do not disclose second and third tubular dilators having knurled outer surfaces. Kambin teaches, in figures 1 and 4-7, dilators with knurled outer surfaces (e.g., at 28 and 36). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kambin, to knurl outer surfaces of the second and third tubular dilators of Smith. Such a modification would provide firmer gripping surfaces for manipulation of the dilators.
7. Claims 22, 23, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson (4,545,374) in view of Ma et al. (3,848,601). Jacobson discloses the invention substantially as claimed, in col. 5, line 45 to col. 11, line 49, a method for fixing adjacent vertebrae, where skin and tissue are sequentially dilated to provide access portals and discectomies are performed through the portals. However, Jacobson does not disclose fusing adjacent vertebrae with bone graft material

introduced through the portals, and Jacobson does not disclose visualizing the disk space and the delivery of bone graft material though the second access portal. Ma et al. teach, in col. 1, lines 5-66, col. 5, lines 26-34, and col., 6, lines 50-54, the introduction of graft material through portals in dilated tissue and the visualization of the disk space and bone graft material through a portal (with the aid of a Penfield probe and X-ray film). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Ma et al., to introduce bone graft material into the portals created by the method of Jacobson, and it would have been obvious to visualize a portal and the bone graft material delivered through the portal. Bone graft material provides a well-known means for interbody fusion, and visualization of disk and the bone graft material through a portal allows assessment of the vertical height of the interspace between fused vertebrae.

Allowable Subject Matter

8. Claims 30-33 are allowed.
9. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a surgical system with at least three dilators, each including a bore therethrough, at least one bone screw, and an elongated fixation element extendable between the adjacent vertebrae and engageable with a bone screw.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

10. Claims 20, 21, 25, and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a dilator system with three tubular dilators and a bone screw sized to be received in one of the dilators. The prior art of record also does not disclose a method for fixing adjacent vertebrae, where skin and tissue are sequentially dilated and adjacent vertebrae are fused with a material in a portal created by the dilated skin and tissue, where fixation instrumentation is secured to the pedicles of the adjacent vertebrae, and where at least three dilator tubes are used to dilate the skin and tissue.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

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Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.



Julian W. Woo
Primary Examiner

August 12, 2003